K092414

MAR 1 0 2010

510(k) Summary of Safety and Effectiveness

ConMed™ Detachatip® Instrument Trays

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 510(k) Number _____

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502
Registration Number: 1320894
Date: August 6, 2009

B. Company Contact

Sandy Coveleski
Regulatory Affairs Specialist
ConMed Corporation
525 French Road
Utica, NY 13502

Phone: 315-624-3435
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e-mail: sandy_coveleski@mail.conmed.com

C. Device Name

Trade Name:	CONMED™ DETACHATIP® INSTRUMENT TRAYS
Common Name:	Instrument Sterilization Tray
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes, and other Accessories
Proposed Class/Device:	Class II
Product Code:	KCT
Regulation Number:	21 CFR 880.6850
Panel:	880 General Hospital

D. Predicate Device

Paragon Medical Surgical Instrument Delivery Tray
Paragon Medical
510(K) # K032119

E. Intended Use

The **ConMed™ DetachaTip® Instrument Trays** are perforated containment devices for medical device sterilization. **ConMed™ DetachaTip® Instrument Trays** are a family of containment devices used to conveniently organize, sterilize, and transport Detachatip instruments between uses. The ConMed instrument trays are not intended to maintain sterility. We do not recommend that the trays be used to store sterilized contents.

The 33cm DetachaTip Instrument Tray (1-1027) is designed for use with ConMed's 33cm DetachaTip multiuse scissors, DetachaTip multiuse graspers, DetachaTip multiuse dissectors and DetachaTip handles. The trays are intended to be used specifically with the following:

CAT. NO.	DESCRIPTION
2-1003	METZENBAUM, 33CM LENGTH
2-1004	MINI- METZENBAUM, 33CM LENGTH
2-1005	5MM BABCOCK GRASPER, 33CM LENGTH
2-1008	FENESTRATED GRASPER, 33CM LENGTH
2-1009	CURVED DISSECTOR, 33CM LENGTH
1-1010	STANDARD HANDLE
2-1013	HOOK, 33CM LENGTH
2-1014	10MM BABCOCK, 33CM LENGTH
1-1015	COMPACT HANDLE
2-1017	RIGHT ANGLE MEEKER DISSECTOR 33CM
2-1018	TAPERED DISSECTOR, 33CM LENGTH
2-1019	ALLIS GRASPER, 33CM LENGTH
1-1024	IN-LINE HANDLE
1-1028	ENDOWEAVE GRASPER, 33 CM LENGTH

The 43cm DetachaTip Instrument Tray (1-4327) are designed for use only with ConMed's 43cm DetachaTip multiuse scissors, DetachaTip multiuse graspers, DetachaTip multiuse dissectors and DetachaTip handles. The trays are intended to be used specifically with the following:

CAT. NO.	DESCRIPTION
2-4301	METZENBAUM, 43CM LENGTH
2-4304	MINI- METZENBAUM, 43CM LENGTH
2-4305	5MM BABCOCK GRASPER, 43CM
2-4308	CURVED DISSECTOR, 43CM LENGTH
2-4307	FENESTRATED GRASPER, 43CM LENGTH
2-4314	10MM BABCOCK, 43CM
2-4317	RIGHT ANGLE MEEKER DISSECTOR 43CM
2-4318	TAPERED DISSECTOR, 43CM
2-4319	ALLIS GRASPER, 43CM
2-4328	ENDOWEAVE GRASPER, 43CM

Materials The ConMed™ DETACHATIP® INSTRUMENT TRAYS consist of a Radel R Polyphenylsulfone base, a Radel R Polyphenylsulfone tray, a silicone rubber mat, a Radel R Polyphenylsulfone lid with tray lid clips with perforations to facilitate steam penetration, and stainless steel carrying handles. The tray holds the ConMed™ DETACHATIP® surgical instruments before, during, and after the sterilization process. The tray set has a locking lid to contain the instruments.

Sterilant Penetration The the ConMed™ DETACHATIP® INSTRUMENT TRAYS have been validated to perform effectively during prevacuum steam sterilization and drying cycles, using biological indicators and thermocouples to support sterilization and drying processes.

Pre-vacuum
Min temperature =132°C
Min. exposure = 4 minutes
Min. dry time = 20 minutes

CAUTION: Testing demonstrates that a minimum dry time of 20 minutes is required to prevent wet packs when using the prevacuum cycle.

Note: Validation was conducted using wrapped trays. The device should be used only in conjunction with FDA cleared wrap indicated for these sterilization cycles.

Shelf Life The sterilization tray is reusable and will not be serviced or repaired.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Sandy Coveleski
Regulatory Affairs Specialist
ConMed Corporation
525 French Road
Utica, New York 13502

MAR 10 2010

Re: K092414
Trade/Device Name: ConMed™ DetachaTip® Instrument Trays
33cm DetachaTip Instrument Tray (1-1027)
43cm Detachatip Instrument Tray (1-4327)
Regulation Number: 21CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: February 16, 2010
Received: February 17, 2010

Dear Ms. Coveleski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): 092414

Family Name: **ConMed™ DetachaTip® Instrument Trays**
Trade Name: 33cm DetachaTip Instrument Tray (1-1027)
43cm DetachaTip Instrument Tray (1-4327)

Indications for Use

The **ConMed™ DetachaTip® Instrument Trays** are perforated containment devices for medical device sterilization. **ConMed™ DetachaTip® Instrument Trays** are a family of containment devices used to conveniently organize, sterilize, and transport Detachatip instruments between uses. The ConMed instrument trays are not intended to maintain sterility. We do not recommend that the trays be used to store sterilized contents.

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Cat. No.	Description
2-1003	Metzenbaum, 33cm length
2-1004	Mini- Metzenbaum, 33cm length
2-1005	5mm Babcock Grasper, 33cm length
2-1008	Fenestrated Grasper, 33cm length
2-1009	Curved Dissector, 33cm length
1-1010	Standard Handle
2-1013	Hook, 33cm length
2-1014	10mm Babcock, 33cm length
1-1015	Compact Handle
2-1017	Right Angle Meeker dissector 33cm
2-1018	Tapered Dissector, 33cm length
2-1019	Allis Grasper, 33cm length
1-1024	In-line Handle
1-1028	Endoweave Grasper, 33 cm length

The 43cm DetachaTip Instrument Tray (1-4327) are designed for use only with ConMed's 43cm DetachaTip multiuse scissors, DetachaTip multiuse graspers, DetachaTip multiuse dissectors and DetachaTip handles. The trays are intended to be used specifically with the following:

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Cat. No.	Description
2-4301	Metzenbaum, 43cm length
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2-4319	Allis Grasper, 43cm
2-4328	Endoweave Grasper, 43cm

Sterilize the 33cm DetachaTip Instrument Tray (1-1027) and the 43cm DetachaTip Instrument Tray (1-4327) using the following parameters:

Method	Cycle	Temperature	Exposure Time	Dry Cycle Time
Steam (wrapped)	Pre-vacuum	270°F(132°C)	4 minutes	20 minutes

Prescription Use___ AND/OR (Part 21 CFR 801 Subpart D)

Over-the-Counter Use__X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Queen-Wells

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092414